K041042

JUL 16 2004

Split Septum Injection Sites
"Special" 510(k) Premarket Notification

510K Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the Fresenius Combiset with Access Flow Reversing Connector.

Company: Fresenius Medical Care North America
95 Hayden Ave.
Lexington, MA 02420
Date: April 20, 2004
Trade Name: Split Septum Injection Sites
Common Name: Blood Tubing for Hemodialysis
Classification Name and Reference: 21 CFR §876.5820 Blood Tubing Set, with or without Anti-Regurgitation Valve – Class II
Device Product Code and Panel Code: KOC, 78 and FJK, 78
Predicate Device(s):

- Fresenius CombiSets® Hemodialysis Blood Tubing Sets; K962081, SE 11/01/96
- Fresenius CombiSets® Hemodialysis Blood Tubing Sets; K001107, SE 06/23/00
- Fresenius CombiSets® Hemodialysis Blood Tubing Sets; K000451, SE 05/09/00
- Fresenius Arterial Blood Tubing Sets; K971313, SE 10/27/97
- Fresenius Venous Blood Tubing Sets; K971687, SE 07/29/97
- Fresenius Single Use Arterial Bloodline Sets with Alternate Pump Segment Material, K012242, 08/16/01

Description:
The Split Septum Injection Sites are designed for use during hemodialysis with either a 21 gauge metal needle or plastic needles that have a 19½ priming volume. The injection site plug features a tapered split to accommodate either needle described above. This is the only change to the Fresenius Hemodialysis Blood Tubing Sets currently offered. The housing and septa are identical to that of the current standard injection site.

Intended Use:
Venous Blood Tubing Set
The Fresenius Venous Bloodlines are intended for use as the extracorporeal blood circuit during Hemodialysis. It is intended for single only use. The Hemodialysis Venous Blood Tubing Set is indicated for use with conventional and high flux negative pressure hemodialyzer equipment.
Arterial Blood Tubing Set
The Fresenius Arterial Bloodlines are intended for use as the extracorporeal blood circuit during Hemodialysis. It is intended for single only use. The Fresenius Bloodlines are intended to for use with Hemodialysis arterial blood tubing sets in conventional and high flux negative pressure hemodialyzer equipment.
CombiSets Hemodialysis Blood Tubing Set
The Fresenius CombiSets are intended for use as the extracorporeal blood circuit during Hemodialysis. They are intended for single use only. The CombiSets are indicated for use with conventional and high flux negative pressure hemodialyzer equipment.

Safety and Performance:
The intended use, technological characteristics, design features, and materials are substantially equivalent to the predicate device. In support of this Special 510K, Fresenius Medical North America has provided certification of compliance to 21 CFR 820.30-Design Control requirements, and a summary of the results of validation testing (performance testing) for the minor device modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Mr. Arthur Eilinsfeld
Director, Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K041042
Trade/Device Name: Fresenius Split Septum Injection Sites
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Product Code: 78 FJK and KOC
Regulation Number: 21 CFR §880.5440
Regulation Name: Intravascular administration set
Product Code: 78 FPA
Regulatory Class: II
Dated: June 15, 2004
Received: June 16, 2004

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fresenius Medical Care

Indications for Use Statement

Device Name:

Split Septum Injection Sites (a component of Fresenius Bloodlines)

Indications for Use:

CombiSets Hemodialysis Blood Tubing Set
The Fresenius CombSets are intended for use as the extracorporeal blood circuit during Hemodialysis. They are intended for single use only. The CombiSets are indicated for use with conventional and high flux negative pressure hemodialyzer equipment.

Venous Blood Tubing Set
The Fresenius Venous Bloodline is intended for use as the extracorporeal blood circuit during Hemodialysis. It is intended for single only use. The Hemodialysis Venous Blood Tubing Set is indicated for use with conventional and high flux negative pressure hemodialyzer equipment.

Arterial Blood Tubing Set
The Fresenius Arterial Bloodline is intended for use as the extracorporeal blood circuit during Hemodialysis. It is intended for single only use. The Fresenius Arterial Bloodline is intended to for use with conventional and high flux negative pressure hemodialyzer equipment.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

Fresenius Medical Care North America
Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041042